IN THE CLAIMS

This listing of the claims replaces all prior versions of the claims in the application.

1-11. (Canceled)

12. (Currently amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 or variant thereof in combination with a dosing regimen for said anti-HER2 antibody or fragment thereof, wherein said dosing regimen for said anti-HER2 antibody or fragment thereof comprises administering to said subject at least one therapeutically effective dose of said anti-HER2 antibody or fragment thereof, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 activates NK cells and ~~has~~ comprises an amino acid sequence having at least ~~70%~~ 90% sequence identity to SEQ ID NO:1 ~~with said IL-2~~ as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said ~~fragment of said~~ anti-HER2 antibody or fragment thereof ~~retains the ability of said anti-HER2 antibody to bind~~ binds to the extracellular domain of the HER2 receptor protein.

13. (Previously presented) The method of claim 12, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

14. (Previously presented) The method of claim 13, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0

mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

15. (Previously presented) The method of claim 14, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

16. (Currently amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of said anti-HER2 antibody or fragment thereof within 6 days of said first administration of said therapeutically effective dose of said IL-2 or variant thereof to said subject, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 activates NK cells and ~~has~~ comprises an amino acid sequence having at least ~~70%~~ 90% sequence identity to SEQ ID NO:1 ~~with said IL-2~~ as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said ~~fragment of said~~ anti-HER2 antibody or fragment thereof ~~retains the ability of said anti-HER2 antibody to bind~~ binds to the extracellular domain of the HER2 receptor protein.

17. (Currently amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of said anti-HER2 antibody

or fragment thereof and a therapeutically effective dose of said IL-2 or variant thereof, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 activates NK cells and ~~has~~ comprises an amino acid sequence having at least ~~70%~~ 90% sequence identity to SEQ ID NO:1 ~~with said IL-2~~ as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said ~~fragment of said~~ anti-HER2 antibody or fragment thereof ~~retains the ability of said anti-HER2 antibody to bind~~ binds to the extracellular domain of the HER2 receptor protein.

18. (Previously presented) The method of claim 17, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of said anti-HER2 antibody or fragment thereof on day 7 of said introductory cycle.

19. (Previously presented) The method of claim 18, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody or fragment thereof on day 1 of said subsequent cycle.

20. (Previously presented) The method of claim 18, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises

administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

21. (Previously presented) The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

22. (Previously presented) The method of claim 12, wherein said IL-2 or variant thereof is administered subcutaneously.

23. (Previously presented) The method of claim 12, wherein said anti-HER2 antibody comprises at least one human constant region.

24. (Currently amended) The method of claim 12, wherein said anti-HER2 antibody is selected from the group consisting of a humanized anti-HER2 antibody, a chimeric anti-HER2 antibody, or a human anti-HER2 antibody~~, and said fragment thereof retains the ability of said humanized, chimeric, or human anti-HER antibody to bind the HER2 receptor protein~~.

25. (Currently amended) The method of claim 12, wherein said anti-HER2 antibody is a humanized~~,~~ or chimeric~~, or human~~ form of a murine antibody selected from the group consisting of 4D5 and 520C9.

26. (Previously presented) The method of claim 12, wherein said therapeutically effective dose of said IL-2 or variant thereof is administered as a pharmaceutical composition selected from the group consisting of a monomeric IL-2 pharmaceutical composition, a multimeric pharmaceutical IL-2 composition, a lyophilized IL-2 pharmaceutical composition, and a spray-dried IL-2 pharmaceutical composition.

27. (Currently amended) The method of claim 26, wherein said IL-2 or variant thereof is recombinantly produced ~~and said IL-2 is human IL-2~~.

28. (Previously presented) The method of claim 27, wherein said variant of human IL-2 is des-alanyl-1, serine-125 human interleukin-2.

29. (Previously presented) The method of claim 28, wherein said anti-HER2 antibody or fragment thereof comprises at least one human constant region.

30. (Currently amended) The method of claim 28, wherein said anti-HER2 antibody is selected from the group consisting of a humanized anti-HER2 antibody, a chimeric anti-HER2 antibody, or a human anti-HER2 antibody~~, and said fragment thereof retains the ability of said humanized, chimeric, or human anti-HER antibody to bind the HER2 receptor protein~~.

31. (Currently amended) The method of claim 28, wherein said anti-HER2 antibody is a humanized~~,~~ or chimeric~~, or human~~ form of a murine antibody selected from the group consisting of 4D5 and 520C9.

32. (Previously presented) The method of claim 16, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

33. (Previously presented) The method of claim 32, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

34. (Previously presented) The method of claim 33, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

35. (Previously presented) The method of claim 17, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

36. (Previously presented) The method of claim 35, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

37. (Previously presented) The method of claim 36, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m^2 and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

38. (Previously presented) The method of claim 18, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

39. (Previously presented) The method of claim 38, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

40. (Previously presented) The method of claim 39, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

41. (Currently amended) The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 ~~mIU~~ MIU/m^2.

42. (Currently amended) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said concurrent therapy comprises daily administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of an introductory cycle through day 20 of said introductory cycle, and a single administration of a therapeutically effective dose of said anti-HER2 antibody or fragment thereof on day 7 of said introductory cycle; wherein said variant of said IL-2 activates NK cells and ~~has~~ comprises an amino acid sequence having at least ~~70%~~ 90% sequence identity to SEQ ID NO:1 ~~with said IL-2~~ as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said ~~fragment of said~~ anti-HER2 antibody or fragment thereof ~~retains the ability of said anti-HER2 antibody to bind~~ binds to the extracellular domain of the HER2 receptor protein.

43. (Previously presented) The method of claim 42, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or biologically active variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2.

44. (Previously presented) The method of claim 43, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

45. (Previously presented) The method of claim 44, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

46. (Previously presented) The method of claim 45, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

47. (Previously presented) The method of claim 42, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody on day 1 of said subsequent cycle.

48. (Previously presented) The method of claim 42, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

49. (Previously presented) The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises

administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

50. (Previously presented) The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

51. (Previously presented) The method of claim 12, wherein said cancer is breast cancer.

52. (Previously presented) The method of claim 51, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.

53. (Currently amended) The method of claim 52, wherein said IL-2 or variant thereof is recombinantly produced~~, and wherein said IL-2 is human IL-2~~.

54. (Previously presented) The method of claim 16, wherein said cancer is breast cancer.

55. (Previously presented) The method of claim 54, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.

56. (Currently amended) The method of claim 55, wherein said IL-2 or variant thereof is recombinantly produced~~, and wherein said IL-2 is human IL-2~~.

57. (Previously presented) The method of claim 17, wherein said cancer is breast cancer.

58. (Previously presented) The method of claim 57, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.

59. (Currently amended) The method of claim 58, wherein said IL-2 or variant thereof is recombinantly produced~~, and wherein said IL-2 is human IL-2~~.

60. (Previously presented) The method of claim 42, wherein said cancer is breast cancer.

61. (Previously presented) The method of claim 60, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 and 520C9.

62. (Currently amended) The method of claim 61, wherein said IL-2 or variant thereof is recombinantly produced~~, and wherein said IL-2 is human IL-2~~.

63. (New) A method of treating a subject for a cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an IL-2 polypeptide comprising the amino acid sequence of SEQ ID NO:1 and a humanized anti-HER2 antibody selected from the group consisting of a humanized 4D5 antibody and a humanized 520C9 antibody, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 polypeptide in combination with a dosing regimen for said humanized anti-HER2 antibody, wherein said dosing regimen for said humanized anti-HER2 antibody comprises administering to said subject at least one therapeutically effective dose of said humanized anti-HER2 antibody, wherein said therapeutically effective dose of said humanized anti-HER2 antibody is in the range from about

1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2.

64. (New) The method of claim 63, wherein said anti-HER2 antibody is a humanized 4D5 antibody.

65. (New) The method of claim 63, wherein said anti-HER2 antibody is a humanized 520C9 antibody.

66. (New) The method of claim 63, wherein said therapeutically effective dose of said humanized anti-HER2 antibody is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is about 1.0 MIU/m^2.

67. (New) The method of claim 63, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of said IL-2 polypeptide on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of said humanized anti-HER2 antibody or fragment thereof within 6 days of said first administration of said therapeutically effective dose of said IL-2 polypeptide to said subject.

68. (New) The method of claim 63, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of said humanized anti-HER2 antibody and a therapeutically effective dose of said IL-2 polypeptide.

69. (New) The method of claim 68, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of IL-2 polypeptide and said therapeutically effective dose of said humanized anti-HER2 antibody during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of said IL-2 polypeptide on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of said humanized anti-HER2 antibody on day 7 of said introductory cycle.

70. (New) The method of claim 63, further comprising administering said therapeutically effective dose of said IL-2 polypeptide and said therapeutically effective dose of said humanized anti-HER2 antibody during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 polypeptide on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said humanized anti-HER2 antibody on day 1 of said subsequent cycle.

71. (New) The method of claim 63, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 polypeptide an intermediate dose of said IL-2 polypeptide, wherein said intermediate dose is about 12.0 MIU/m^2.

72. (New) The method of claim 63, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 polypeptide an intermediate dose of said IL-2 polypeptide, wherein said intermediate dose is about 12.0 MIU/m^2.

73. (New) The method of claim 63, wherein said IL-2 polypeptide is administered subcutaneously.